95

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/433,429	11/04/1999	SHAUN A. KIRKPATRICK	11160	2571

7590 07/22/2004

LEOPOLD PRESSER
SCULLY SCOTT MURPHY & PRESSER
400 GARDEN CITY PLAZA
GARDEN CITY, NY 11530

EXAMINER	
NGUYEN, QUANG	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/433,429	KIRKPATRICK, SHAUN A.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2004 and 16 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,25,26 and 29-32* is/are pending in the application.

4a) Of the above claim(s) *1-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,26 and 29-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 5/27/04 has been entered.

Claims 1-17, 25-26 and 29-32 are pending in the present application.

This application contains claims 1-17 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Amended claims 25-26 and 29-32 are examined on the merits herein.

Response to Applicant's amendment

The rejection under 35 USC 101 is withdrawn in light of Applicant's amendment.

The rejections under 23 USC 112, first paragraph (Written Description and Enablement), are withdrawn in light of Applicant's amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25-26, 29 and 32 stand rejected under 35 U.S.C. 102(b) as being anticipated by Gorman (EP 0 260 148 A2; Cited previously) for the same reasons already set forth in the previous Office Action mailed on 2/24/04 (pages 8-10).

Claim 25 stands rejected under 35 U.S.C. 102(b) as being anticipated by Jiang et al. (Gene 185:285-290, 1997; Cited previously) for the same reasons already set forth in the previous Office Action mailed on 2/24/04 (page 10).

Claim 25 stands rejected under 35 U.S.C. 102(b) as being anticipated by Blanchard et al. (Biology of Reproduction 56:495-500, 1997; Cited previously) for the same reasons already set forth in the previous Office Action mailed on 2/24/04 (pages 10-11).

Response to Arguments

Applicant's arguments related to the above rejections in the Amendment filed on 5/27/04 (pages 7-8) have been fully considered, but they are respectfully found to be unpersuasive.

Applicant argues that none of the cited references teaches an isolated Sertoli cell comprising a vector which functions in a Sertoli cell operatively linked to a coding sequence for a biological protein wherein the Sertoli cell creates an immunological privileged site *in vivo*. With respect to claim 32, Applicant further argues that Sertoli cells isolated from a transgenic non-human animal generally have the heterologous coding sequence stably integrated in the genome and are typically uniform in the expression of the heterologous biological protein, and such Sertoli cells are distinct from Sertoli cells transfected *in vitro*, and may or may not harbor the heterologus-coding sequences in the genome.

Firstly, Applicant fails to point out exactly which element(s) of the claims that the cited references do not teach or disclose. The references clearly disclose Sertoli cells comprising an expression vector encoding a biological protein. It should be noted that it is the inherent property of a Sertoli cell to be able to create an immunologically privileged site *in vivo*. Please, also note that where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). Applicant fails to prove that genetically modified Sertoli cells of the cited references do not necessarily or inherently possess the characteristics of the isolated Sertoli cell being claimed by the present invention.

Secondly, with respect to claim 32 Gorman clearly disclosed the establishment of permanent mouse Sertoli TM4 cell lines that provide continuous production of factor VIII (after rounds of selection and amplification; see example 2 under the section of "Continuous production"). Thus, these genetically modified Sertoli cells must have the heterologous sequence encoding factor VIII being stably incorporated into their genomes. There is no evidence that cells within a single genetically modified Sertoli

TM4 cell line or cell clone taught by Gorman would have variable expression levels of factor VIII. Moreover, please also note the claims are drawn to an isolated Sertoli cell. Therefore, the genetically modified Sertoli cells of Gorman are indistinguishable from the genetically modified Sertoli cells isolated from a non-human transgenic animal.

Accordingly, the claims stand rejected for the same reasons already set forth in the previous Office Action mailed on 2/24/04.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30 and 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gorman et al. (EP 0 260 148 A2; Cited previously) in view of Meulien (U.S. Patent No. 5,521,070; Cited previously) for the same reasons already set forth in the previous Office Action mailed on 2/24/04 (pages 11-14).

Response to Arguments

Applicant's argument related to the above rejection in the Amendment filed on 5/27/04 (pages 8-9) has been fully considered, but it is respectfully found to be unpersuasive.

Applicant argues basically that Meulien does not cure the deficiencies of Gorman that are set forth in the response to the rejection of claims 25-26, 29 and 32 above.

The only deficiency that Gorman does not teach is a vector comprising a coding sequence for factor IX, and that this deficiency is cured by the teachings of Meulien. Otherwise, Gorman teaches every other elements of an isolated genetically modified Sertoli cell of the presently claimed invention (please see response to Applicant's argument for the rejection of claims 25-26, 29 and 32 above).

Claims 30 and 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gorman (EP 0 260 148 A2; Cited previously) in view of Ciotti et al. (Biochemistry 35:10119-10124, 1996; Cited previously) for the same reasons already set forth in the previous Office Action mailed on 2/24/04 (pages 14-16).

Response to Arguments

Applicant's argument related to the above rejection in the Amendment filed on 5/27/04 (pages 9-10) has been fully considered, but it is respectfully found to be unpersuasive.

Applicant argues basically that Ciotti et al. does not cure the deficiencies of Gorman that are set forth in the response to the rejection of claims 25-26, 29 and 32 above.

The only deficiency that Gorman does not teach is a vector comprising a coding sequence for bilirubin UDP-glucuronosyltransferase, and that this deficiency is cured by the teachings of Ciotti et al. Otherwise, Gorman teaches every other elements of an isolated genetically modified Sertoli cell of the presently claimed invention (please see response to Applicant's argument for the rejection of claims 25-26, 29 and 32 above).

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Quang Nguyen, Ph.D.

DAVID GUZO
PRIMARY EXAMINER